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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985
23535	7590	06/30/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary**Application No.**

09/751,059

Applicant(s)

BAKER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/01/02 06/25/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of change of power of attorney filed 05/07/02, IDS and supplemental ID filed 06/25/02 and 07/01/02 respectively, formal drawing and executed declaration filed in response to the letter to file missing parts filed 06/04/01 and 04/09/01 respectively, request for extension of time filed 06/04/01, and request for status of application filed 12/02/02 and 01/20/04 respectively.

Priority

Applicants claim continuation-in-part for application serial number 09/474,866, which was filed 12/30/1999. It is noted that the application serial number 09/474,866 was abandoned 04/17/000 during pre-examination processing and abandoned before the filing of application serial number 09/561,111, which was filed 04/28/00. Applicants are respectfully requested to comment on this.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15, 16, 18, 19, 28, 29 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 16, 18, 19, 28, 29 and 44 contain the trademark/trade name "TRITON", "TYLOXAPOL", "POLYSORBATE" and "TWEEN", . Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte*

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Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe specific surfactant trademarked by companies and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 6-10, 14-18, 20, 23, 25, 26, 28-31, 33, 35-38, 40, 42, 44, 46-53, 55-57, 61-63, 65 and 67-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker, Jr. et al. (US 6,015,832).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Baker discloses methods of inactivating bacterial spores where the method comprises contacting the bacteria or bacteria containing surfaces and objects with an oil-in-water emulsion composition; the oil-in-water emulsion composition comprises a surfactant such as sodium dodecyl sulfate, organic phosphate based solvent such as tri-n-butyl phosphate, carrier oil and oligopeptides (abstract, column 2, lines 14-47, column 3, lines 5-15). The oils used are water immiscible oils such as squalene oil, fish oils, canola oil, rapeseed oil, corn oil and flavor oils (column 2, lines 53-57); the surfactants are TWEEN, TRITON, which is a pheoxypolyethoxyethanol (column 3, lines 1-4). Baker also discloses method of treating a subject by applying pharmaceutically suitable bacteria inactivating composition topically to skin surfaces, mucous membranes, oral surfaces and to wounds and the composition will typically be a cream, gel, spray or mouthwash (column 3, lines 21-29). Furthermore, Baker discloses that the emulsion composition can be used to inactivate bacterial spores by topical application of the emulsion to skin or mucous membranes (column 3, lines 29-39) and can be used to inactivate bacteria and bacterial spores on surfaces that come in contact with the human and vehicles and instruments are examples of surfaces that can be decontaminated (column 3, lines 40-49). While Baker discloses evaluating the efficacy of the composition on bacterial spores by biological assay, and although Baker discloses adding sterile saline to either the culture or the emulsion (column 9, lines 3-25 and column 10, lines 23-53), Baker fails to classify the process as modifying the emulsion and it is respectfully submitted the process modifies the composition in preparation for analysis. Baker meets the limitations of the claims.

5. Claims 1, 3-6, 8-10, 15-23, 27-30, 32-36, 39, 40, 43-53, 60-63, 65, 67 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz (US 6,117,415).

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Schwarz discloses submicron oil-in-water emulsion that is used for prolonged delivery of antibacterial compound (column 1, lines 8-14). The emulsion contains oil selected from olive oil, corn oil, squalene and fish oils (column 2, lines 25-38); the emulsion contains surfactants such as polyethylene glycol, sodium lauryl sulfate, TWEEN, TRITON and TYLOXAPOL (column 2, lines 39-53 and column 6, line 64); glycerol (examples 1 and 2); and antibacterial components such as triclosan, benzalkonium chloride, cetyltrimethylammonium bromide and cetylpyridinium chloride (column 3, lines 5-8). Emulsions are discontinuous by virtue of the suspended particles contained in the emulsion/suspension. Schwarz meets the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11-13, 37 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832).

Baker discloses the instant anti-microbial composition. Baker fails to disclose the limitations of claims 12 and 13. Regarding claims 11, 37 and 66, one oil type can be replaced with another oil type with the expectation that oil-in-water emulsion would provide the desired function as an anti-microbial. Regarding the amounts of the oil phase, differences in amounts of the oil phase will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. There is no demonstration in

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applicants' specification that the amounts recited in the said claims provide unusual results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the oil-in-water emulsion of Baker. One having ordinary skill in the art would have been motivated to optimize the composition of Baker with the expectation of producing oil-in-water emulsion that would provide the desired inactivation of bacteria.

8. Claims 24, 41, 54 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz (US 6,117,415).

Schwarz disclose the instant oil-in-water emulsion composition. Schwarz does not disclose using the emulsion in a food area. Regarding claims 24 and 41, glucose or fructose is listed in applicants' specification as germination enhancers and glucose and fructose can be sweeteners. Since the product of Schwarz is a toothpaste, the enhancer can be included in the composition to either mask the taste of the paste or to sweeten the paste for taste improvement purposes. However, since the Schwarz's composition is used in oral care, it would be expected to be safe in food product area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the emulsion of Schwarz and use it as an oral care product. One having ordinary skill in the art would have been motivated to use the emulsion as antibacterial product to disinfect other surface areas including an area of food product with the expectation of non-toxically disinfecting the area.

9. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,015,832).

Baker discloses biologically assaying for the effectiveness of the emulsion composition but does not disclose that the product is for sale. However, it is common knowledge that to sell

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any product requires some form of advertising. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and modify the emulsion of Baker as necessary in the evaluation of the emulsion for effectiveness. One having ordinary skill in the art would have been motivated to advertise the product in order to reach a wide(r) market for sales.

Claims 58 and 59 are directed to method of doing business in an effort to sell a product and these claims appear not to belong with the rest of the claims. The advertisement issue may raise questions of statutory concerns because advertisements may be non-statutory matter and the patentable utility of advertising and selling appear to be lacking. It is respectfully submitted that any pharmaceutical product invention has the ultimate goal of reaching a consumer market that is inherent in the method of doing business or that is an unspoken understood goal of the invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 2, 4-10, 14, 17, 19, 21-23, 28, 30, 31, 33-36, 39, 40 and 44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7-14 and 17 of copending Application No. 09/162,970.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the vaccine composition of the co-pending application encompasses the claimed composition of the examined application. Both compositions are emulsions that contain oil, surfactant and solvent and halogen containing compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1, 9, 10, 17, 19, 21, 22, 24-26, 35, 36, 39 and 41, rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 12-14 of U.S. Patent No. 6,506,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant composition is encompassed in the allowed claimed composition. For example, claims 9, 10, 35 and 36 are encompassed in allowed claim 4.

13. Claims 46-48 and 50-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5 and 10-15 of U.S. Patent No. 6,559,189. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the allowed process of decontaminating an area uses nanoemulsion and the examined process uses emulsion, the effect of both processes would be the same and one emulsion can be used in place of the other with the expectation of achieving the same result.

14. Claims 1, 2, 4, 9, 10, 14, 21, 22 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6-18 of U.S. Patent No. 6,635,676. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the examined claimed composition is encompassed in the allowed claimed composition.

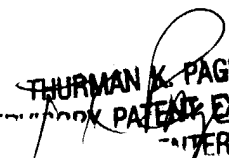
15. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
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